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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,885	03/22/2004	John W. Benbow	PC25078A	2214

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PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
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GROTON, CT 06340

EXAMINER	
TUCKER, ZACHARY C	
ART UNIT	**PAPER NUMBER**
1624	

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/805,885	BENBOW ET AL.	
	Examiner	Art Unit	
	Zachary C. Tucker	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-14 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 22Mar,2Jul04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Requirement for Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, drawn to chemical compounds of formula (I), classified in class/subclass 544/346.

II. Claims 5-9, drawn to a pharmaceutical composition comprising compounds from Group I as set forth above and methods of treating a glycogen synthase kinase 3-mediated condition, disease, or symptom, in a mammal, wherein the sole recited therapeutic agent is a compound as set forth in Group I *supra*, classified in class/subclass 514/250.

III. Claims 10-14, drawn to a pharmaceutical composition comprising compounds from Group I as set forth above and methods of treating a glycogen synthase kinase 3-mediated condition, disease, or symptom, in a mammal, wherein the therapeutic agent includes a compound as set forth in Group I, *supra*, **and** an additional therapeutic agent from at least one of classes i – xii as are recited in claim 9. A definitive class and subclass cannot be assigned to this Group, as the U.S. patent classification depends on the *chemical* identity of the therapeutic agent(s), which is not set forth in claim 9, from which 11-14 depend. Only functional language describes those additional therapeutic agents *.

The inventions are independent or distinct, each from the other because:

Inventions I and II and I and III are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1)

the processes for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the methods of Groups II and III could be practiced with materially different therapeutic agents. For example, condition (1) is met in that diabetes is treated with insulin and cancer is treated with a cytotoxic agent, or diabetes is treatable with *combinations* of different hypoglycemic agents; cancer is treatable with a *combination* of surgery and cytotoxic agents. Pharmaceutical combinations as are set forth as part of Groups II and III represent sub-products patentably distinct from the chemical compounds *per se*. Additionally, condition (2) is met by virtue of the chemical compounds as set forth in Group I's utility as biochemical tools for quantification of glycogen synthase kinase 3 *in vitro*, or comparison with other inhibitors of the enzyme for relative potencies of inhibitory activity (see pages 53-54 of the instant specification).

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art and separate classification, because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This Requirement is Further Set Forth as Follows:

Applicant is required under 35 U.S.C. 121 to elect a *single disclosed species* of formula (I), for prosecution on the merits, to which the claims shall be restricted if no generic claim is finally held to be allowable, regardless of whether Group I, II or III is elected. If applicants desire to elected Group II or III in response to this Requirement,

the specie of formula (I) with which the method is practiced is to be elected.

Because every variable included in formula (I), claim 1, is so widely variable, the breadth of the claim is such that examination thereof in the absence of applicants' election of a *single species* of the genus claimed, as a starting point for examination, would place an undue burden on the examiner. A search of the full scope of instant claim 1 is not precluded by an election of a single disclosed species, but is not likely to be completed in the preparation of the first Official action on the merits, especially if prior art anticipating or rendering obvious some part of the claim is found in the examiner's search of the prior art.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

This Requirement is Subject to the Following Condition:

The examiner has required restriction between compounds, pharmaceutical compositions, and method of use claims. Where applicant elects claims directed to compounds, and a compound claim is subsequently found allowable, withdrawn pharmaceutical composition claims and method of use claims that depend from or

otherwise include all the limitations of the allowable compound claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Pharmaceutical composition claims and method of use claims that depend from or otherwise include all the limitations of the patentable compound** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the compound claims and the rejoined pharmaceutical composition claims and method of use claims will be withdrawn, and the rejoined pharmaceutical composition and method of use claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected compound claim is found allowable, an otherwise proper restriction requirement between compound claims, pharmaceutical composition claims and method of use claims may be maintained. Withdrawn pharmaceutical composition claims and method of use claims that are not commensurate in scope with an allowed compound claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the pharmaceutical composition claims and method of use claims should be amended during prosecution either to maintain dependency on the compound claims or to otherwise include the limitations of the compound claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Information Disclosure Statement

References cited in applicants' Information Disclosure Statements (IDS), filed 22 March and 2 July 2004, have been considered by the examiner. Signed and initialed forms PTO 1449 to that effect are included with this letter. On both PTO 1449 forms, the number shown in the section headed "U.S. Patent Documents" is not that of an actual U.S. patent, so the first entry on both IDSs is lined through.

On the PTO 1449 form accompanying the IDS filed 22 March 2004, the first reference authored by Colotta et al is cited as having been published in 1991. This has been corrected; the actual year of publication for that reference was 1999.

Conclusion

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species and invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention and specie.

The election of an invention and species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions and/or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions and/or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication should be directed to Zachary Tucker whose telephone number is (571) 272-0677. The examiner can normally be reached Tuesday-Thursday from 8:00am to 4:30pm or Monday from 6:00am to 1:30pm. If Attempts to reach the examiner are unsuccessful, contact the examiner's supervisor, James O. Wilson, at (571) 272-0661.

The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

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